

### **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **Amendments to Claims**

Claims 1-9 stand cancelled without prejudice or disclaimer.

Claim 10 is amended by incorporating the phrase, “wherein the channel is of cross-sectional shape that facilitates closing of the channel once stem is removed therefrom.” No new matter is added by the amendment. Support for the amendment can be found throughout the application as filed. For example, support can be found on page 4, paragraph [0017] of the application as filed.

Claims 17-18 are currently being amended to incorporate the phrase “the tab includes a stem attached to the applicator at the breakable connection, the pad includes a channel for slidably receiving the stem wherein the channel is of cross-sectional shape that facilitates closing of the channel once stem is removed therefrom, the tab stem passes through the pad.” Support for this phrase can be found in claim 10 as originally filed and on page 4, paragraph [0017] of the application as filed.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 10-18 are now pending in this application.

#### **Election/Restriction**

Applicant thanks the Office for acknowledging the telephonic restriction requirement. The Office has now taken the position that the amendment to the claims presented in Response filed on January 5, 2009, renders this requirement moot.

Applicant thanks the Office for withdrawing the restriction requirement and for including claims 17-18 in the prosecution.

**Claim Rejections Under 35 U.S.C. § 102(b)**

Claims 10 and 16-18 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Emerit (WO 00/71198, English translation).

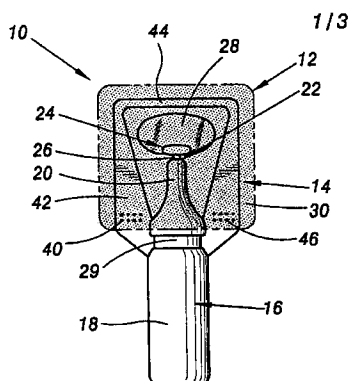
Applicant traverses the rejection for the following reasons:

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Emerit does not teach all the claim elements.

1. Emerit does not teach a tab that has a handle external to the pad.

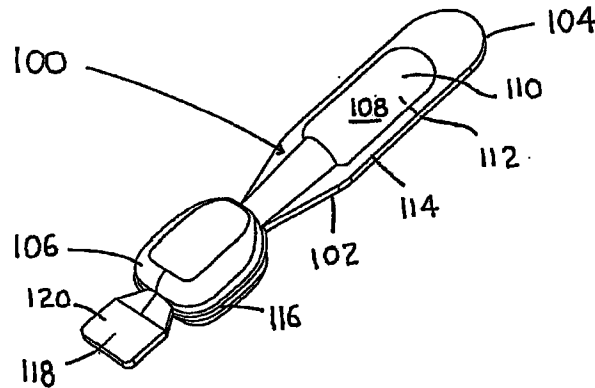
Emerit teaches an applicator where an entire tab including the neck 20, axial exit 22, stopper 24, and actuating projection 28 are all within the absorbent plug or the pledget 12, as shown in Figure 1.



**FIG. 1**

The pledget 12 is formed from a hydrophilic strip 30, for example a strip of gauze (see page 2 of English translation of Emerit). The shearing of the stopper 24 leads to the opening of the cartridge. Therefore, there is no handle to the pledget 12 or the gauze 30 that is external to the pledget or the gauze.

This is in contrast to the claimed invention where the tab 118 comprises a handle portion 120 that is external to the pad 116 (for example, see Figures 1-4).



**FIG. 1**

2. Emerit does not teach separation of the tab from the applicator.

Emerit teaches that an angular displacement of 44 (page 3, ¶6 of English translation of Emerit) causes the shearing of the stopper 24 resulting in the detached portions remaining within the plug 12 (page 3, ¶9 of English translation of Emerit). It is clearly evident from Figures 2 and 3 of Emerit that the tab stays within the pad even after shearing the stopper.

This is in contrast to the claimed invention where the tab separates from the applicator after the detachment of the tab handle from the breakable connection.

The Office alleges that the maintaining means 14 has a portion that extends below the pad 30 which is necessarily gripped when the pad is gripped to break the breakable connection, i.e. nipple 26. According to the Office, this portion is external to the pad.

Firstly, the portion alleged by the Office as being external to the pad is not the portion that is bent to cause the breakage of the stopper. Secondly, this portion does not separate from the applicator but stays attached to it even after the stopper is severed. Therefore, this portion of Emerit is different from the tab handle of the claimed invention which is external to the pad and which separates from the applicator after breakage.

3. Emerit does not teach that the channel is of cross-sectional shape that facilitates closing of the channel once stem is removed therefrom.

Solely to expedite prosecution, Applicant has further amended claims 10, 17 and 18 to incorporate that the channel is of cross-sectional shape that facilitates closing of the channel once stem is removed therefrom. This element of the claim is not taught by Emerit.

In the absence of all the claim elements in Emerit, Applicant requests the Office to withdraw this rejection under 35 U.S.C. § 102(b).

**Claim Rejections Under 35 U.S.C. § 103**

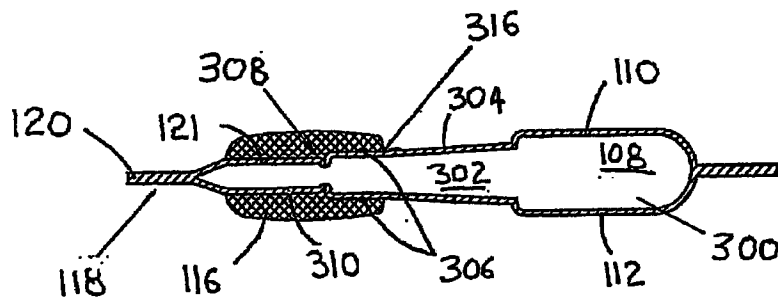
1. Claim 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Emerit.

The Office alleges that even though Emerit does not disclose that the channel in pad 30 is oval in cross section, this channel of oval cross-section can be easily formed when one folds a square piece of material such as pledget 12 in half without a crease. See page 6, last paragraph of Office Action dated 4/1/2009.

As explained above (points 1 and 2), Emerit does not disclose all the claim elements. For this reason alone, this rejection under 35 U.S.C. § 103(a), as allegedly being unpatentable over Emerit, should be withdrawn.

Nevertheless, Applicant respectfully submits that the issue is not whether the oval cross-section can be easily formed, the issue is whether there is any suggestion or motivation in Emerit to modify the applicator of Emerit by folding the pledget in such a way that an oval cross-section is formed. There is no suggestion or motivation in Emerit to incorporate this design in his applicator.

The instant application discloses that the oval-cross-section shape of channel 310 facilitates the closing of the channel 310 by the preferably high density material of pad 116 once stem 121 is removed therefrom (figure 3 below). See page 4, paragraph [0017] of the application as filed.

**FIG. 3**

Therefore, this oval cross-section of the stem assists the channel 310 to close after the stem 121 is pulled out from the channel. This prevents excess of the fluid to leak out in the pad. This closing of the channel is not needed in Emerit since the actuating projection 28 and the stopper 24 stay within the pledget 12 in front of the neck 20 even after the shearing of the stopper 24 from the neck 20. In fact, the closing of the channel in Emerit may prevent a sufficient amount of the fluid to come out of the neck since the neck is already crowded with the actuating projection and the stopper in front of the neck. Hence, there is no suggestion or motivation to a skilled artisan to make the oval cross-section of the neck in Emerit. Further, there is no reasonable expectation of success since the oval cross-section of the neck in Emerit may prevent sufficient amount of the fluid to come out of neck after the shearing of the stopper 24.

For all the reasons as stated above, withdrawal of this rejection is respectfully requested.

2. Claims 12-15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Emerit in view of Jonn et al (U.S. 2002/0037310, "Jonn" herein).

The Office has cited Jonn to fill the deficiency of cyanoacrylate adhesive composition in Emerit alleging that it would be obvious to a skilled artisan to use the applicator of Emerit to dispense a sterilizable tissue adhesive of Jonn. See pages 7-8 of the Office Action dated 4/1/2009.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As explained above, Emerit does not teach or suggest all the claim elements of the applicator of the claimed invention. Jonn is merely cited for the disclosure on cyanoacrylate composition. Therefore, Emerit in combination with Jonn also do not teach or suggest all the claim elements. For this reason alone, withdrawal of this rejection is respectfully requested.

Further, there is no suggestion nor motivation in either of the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

The U.S. Supreme Court, in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007), noted that an invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” The Court held that the teaching, suggestion, motivation “TSM” test must be applied flexibly, and take into account a number of factors “in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed.” *Id.* at 1740-41. Despite this flexibility, however, the Court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does.” *Id.* “To facilitate review, this analysis should be made explicit.” *Id.*

In the absence of any suggestion or motivation in Jonn or Emerit to use Jonn's cyanoacrylate compositions in the applicator of the Emerit, a skilled artisan will have no reason to modify the applicator of Emerit by: a) attaching a handle to the tab where the handle is external to the tab, b) twisting the handle and separating the handle completely from the applicator, c) modifying the neck of Emerit to have the channel of cross-sectional shape that facilitates closing of the channel once stem is removed therefrom, and d) substituting the

antiseptic liquid of Emerit with the cyanoacrylate adhesive of Jonn, and arrive at the claimed invention.

There is simply no reasonable expectation of success to the skilled artisan to carry out the modifications as stated above and expect the applicator to dispense the adhesive composition successfully to the wound site.

For all of the reasons as stated above, Applicant submits that the Office has failed to establish a *prima facie* case of obviousness. Withdrawal of this rejection, under 35 U.S.C. § 103(a) as allegedly being unpatentable over Emerit in view of Jonn, is respectfully requested.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

### CONCLUSION

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

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